Marketing breast milk substitutes: problems and perils throughout the world

June Pauline Brady1,2

ABSTRACT
On 21 May 1981 the WHO International Code of Marketing Breast Milk Substitutes (hereafter referred to as the Code) was passed by 118 votes to 1, the US casting the sole negative vote. The Code arose out of concern that the dramatic increase in mortality, malnutrition and diarrhoea in very young infants in the developing world was associated with aggressive marketing of formula. The Code prohibited any advertising of baby formula, bottles or teats and gifts to mothers or ‘bribery’ of health workers. Despite successes, it has been weakened over the years by the seemingly inexhaustible resources of the global pharmaceutical industry. This article reviews the long and tortuous history of the Code through the Convention on the Rights of the Child, the HIV pandemic and the rare instances when substitute feeding is clearly essential. Currently, suboptimal breastfeeding is associated with over a million deaths each year and 10% of the global disease burden in children. All health workers need to recognise inappropriate advertising of formula, to report violations of the Code and to support efforts to promote breastfeeding; the most effective way of preventing child mortality throughout the world.

INTRODUCTION
In the 19th century breastfeeding was almost universal; however, as Borden developed condensed milk in 1856 and Nestlé produced ‘Farine Lactée’ in 1867, substitute feeding became feasible.1 Over the next 100 years, breastfeeding rates declined as women entered the workforce and formula companies began widespread advertising campaigns.2 In 1944, 88% of Swedish mothers were breastfeeding their infants at 2 months of age; by 1970 the rate had declined to 30%.3 During the 1970s and 1980s breastfeeding rates began to rise in the industrialised world, particularly among older, more educated mothers.2–4 Formula companies responded by vigorously seeking new markets in the developing world.5 They gave gifts to health workers and used saleswomen dressed as ‘nurses’ to provide donations of formula and advice to mothers. Poverty, illiteracy and poor sanitation often led to improper formula preparation. Mortality in very young infants from malnutrition, diarrhoea and pneumonia—virtually unknown previously—increased dramatically.5–8

In resource-poor countries doctors, nurses, health workers and missionaries became increasingly alarmed at this aggressive marketing and rising infant mortality.5–8 Table 1 lists the events leading to the passage of the WHO International Code of Marketing Breast Milk Substitutes (hereafter referred to as the Code).5

Dr Cicely Williams (1893–1992), medical officer in the British Colonial Service (1929–1948), was the first doctor to decry the promotion of breast milk substitutes.9 She maintained that, ‘anyone who, ignorantly or lightly, causes a baby to be fed unsuitable milk, may be guilty of that child’s death’.9 Eventually, 35 years later the tide finally turned with the publication of The Baby Killer by War on Want in the UK.11 It was translated into German with the provocative title of Nestlé Kills Babies.12 Nestlé successfully sued for libel and the authors were required to pay a minimal fine. The judge emphasised that the verdict was not exculpatory and warned Nestlé to reconsider its marketing practices to avoid its products becoming ‘lethally dangerous’.13 A very successful worldwide boycott of Nestlé products (1977–1984) followed.6,15

In 1978, Edward M Kennedy, chairman of the USA Senate Subcommittee on Health and Scientific Research, held a hearing on the promotion and use of infant formula in developing countries.5 He asked, ‘Can a product which requires clean water, good sanitation, adequate family income and a literate parent to follow printed instructions be properly and safely used in areas where water is contaminated, sewage runs in the streets, poverty is severe and illiteracy high?’

The following year WHO and the United Nations Children’s Fund (UNICEF) convened a meeting of 150 participants that included representatives from national governments, UN agencies, non-governmental organisations, the infant food industry and experts on infant feeding.6 Over the next 2 years they drafted a new code to restrict advertising (table 2), which was adopted by the World Health Assembly on 21 May 19819 with 118 votes, three abstentions and one negative vote (the USA).13

Within 3 years of the Code’s passage, 150 countries had passed legislation or formulated policies to restrict advertising.14 Even earlier, in 1977, Papua New Guinea had made formula, bottles or teats available only by prescription.15 However, despite further World Health Assembly resolutions (1986–2010) and the Innocenti declarations (1990 and 2005)16 protecting, promoting and supporting breastfeeding, the pharmaceutical industry has continued to undermine such efforts.17–23 As Coutsoudis et al24 have pointed out, ‘voracious global marketing by the formula-milk industry over the past 60 years has ... dislodged breastfeeding as a viable and desirable strategy for infant feeding’. The fact that annual sales of breast milk substitutes exceed US$31 billion (£20 billion; €24 billion)25 gives the industry little incentive to restrict advertising.
### Review

**Table 1** Events leading to the WHO Code

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1939</td>
<td>Lecture, Singapore Rotary club: <em>Milk and Murder</em> by Cicely Williams.(^{10})</td>
</tr>
<tr>
<td>1972</td>
<td>Article: commerioigenic malnutrition by Jelliffe.(^{8})</td>
</tr>
<tr>
<td>1974</td>
<td>Book: <em>The Baby Killer</em> by Muller.(^{11})</td>
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<tr>
<td>1975</td>
<td>Lawsuit by Nestlé against Swiss AgDW for Nestlé kills Babies(^*^{12})</td>
</tr>
<tr>
<td>1977</td>
<td>International boycott of Nestlé products by INFACT(^{13})</td>
</tr>
<tr>
<td>1978</td>
<td>US Senate: Hearings on Infant Formula. Edward M Kennedy(^{5})</td>
</tr>
<tr>
<td>1979</td>
<td>WHO/UNICEF meeting Infant and young child feeding, Geneva.(^{4})</td>
</tr>
</tbody>
</table>


### VIOLATIONS OF THE CODE

In 2010, 500 violations were documented in 46 countries.\(^{25}\) Figure 1 illustrates a billboard in Asia in violation of the Code. This type of widespread marketing results in mothers’ recognising certain brands and believing their children will be healthier with formula.\(^{26,27}\)

#### Developing countries

Reports of violations are numerous.\(^{17–23}\) In 1998 a study of 3442 mothers and health workers from Dhaka, Durban, Bangkok and Warsaw documented gifts of formula and information violating the Code.\(^{17}\) In a 2003 survey of 186 health-care providers in 43 health facilities in Togo and Burkina Faso, 80% had never heard of the Code.\(^{18}\) In 2004 a survey of 850 mothers and 125 health workers in Uganda cited numerous violations.\(^{19}\) In 2008, 70% of 427 health professionals in Pakistan were unaware of their own breastfeeding laws and 80% unaware of the Code; 12% had received sponsorship from pharmaceutical companies for training sessions or attendance at conferences.\(^{20}\)

Sales of formula are increased when regulations are weak.\(^{21}\) In 2004 the Supreme Court of the Philippines issued a restraining order preventing introduction of the Revised Rules and Regulations of the Milk Code in response to intense lobbying by the pharmaceutical industry,\(^{21–23}\) and consequently formula use increased.\(^{21}\) Although the restraining order was lifted in 2007, the regulations had been weakened to suit the industry.\(^{21–23}\) In contrast, in India where advertising is strictly controlled by the Infant Milk Substitutes Act,\(^{28}\) exclusive breastfeeding at 4–5 months of age is 46% almost three times higher than that of the Philippines.\(^{21,29}\)

#### Industrialised Countries

Many companies still provide free meals, research grants and financial support for conferences to doctors.\(^{30}\) Marketing is more subtle than in developing countries. In countries such as the UK and Australia, where advertising baby formula is prohibited, they circumvent regulations by marketing follow-on formulas that they maintain are not a breast milk substitute but a weaning milk.\(^{14,25,31}\) A distinction many mothers do not understand.\(^{31}\) In the UK, where the rate of exclusive breastfeeding\(^ (7% \text{ at } 4 \text{ months})^2\) is one of the lowest in the world, companies spend 10 times more on advertising than the Department of Health spends on promoting breastfeeding.\(^{32}\) In Norway, by contrast, the rate is 64% at 4 months and advertising is strictly controlled.\(^{5,33}\) Interestingly, 20% of mothers in the UK who were weaning their babies at 4–6 months of age thought formula was better and more nutritious than breast milk.\(^{4}\)

### Reporting violations

Four major non-governmental organisations document and publish violations of the Code: in the UK, the Baby Milk Action and the Inter-Agency Group on Breastfeeding Monitoring; in Canada, the Infant Feeding Action Coalition (INFACT); and in Malaysia, the International Baby Food Action Network (IBFAN), the largest with 200 groups in 95 countries.\(^{25}\) In their 2011 report, *State of the Code by Country*, IBFAN lists 67 developing countries (including India, Pakistan, Uganda and Ghana) that have passed laws including all or many of the provisions of the Code. In Europe, however, only six countries (Norway, Serbia, Luxembourg, Albania, Azerbaijan and Georgia) have passed such laws.\(^{33}\) A total of 14 countries, including the USA, have taken virtually no legal action.\(^{35}\) IBFAN publishes a list of violations every 3 years. However, for penalties to be effective, they must be sufficient, consistent and enforced.\(^{34}\) A single international agency that is transparent and sustainable is urgently needed.\(^{34}\) The importance of such an agency is underscored by the global estimate that suboptimal breastfeeding is responsible for 15% of child mortality and 10% of child disease.\(^{35,36}\)

### MORBIDITY AND MORTALITY

#### Developing countries

Numerous studies have documented the increase in morbidity and mortality in developing countries from breast milk substitutes.\(^{35–41}\) Lamberti and associates,\(^{41}\) in a recent meta-analysis of 18 studies from the developing world, compared breast milk substitutes with exclusive or predominant breastfeeding. The relative risk of dying from diarrhoea during the first 5 months of life was 10.52 (95% CI 2.79 to 39.6); from 6 to 12 months it was still 2.18 (95% CI 1.14 to 4.16). One of the highest death rates was seen in Pakistan, where the RR of dying from an infectious disease in the first month was 21.8 (95% CI 7.9 to 57.7).\(^{37,40}\) Early initiation of breastfeeding is critical. In a Ghanaian study, neonatal mortality in babies fed after the first 24 h was over twice that of those fed within the first hour (adjusted OR 2.88, 95% CI 1.87 to 4.42).\(^{38}\)

#### Industrialised countries

Two recent reviews\(^ 2,42\) have summarised studies from the industrialised world where breast milk substitutes have
minimal effect on mortality but significant short-term and long-term effects on morbidity. Failure to breastfeed increases the risk of gastrointestinal disease, acute otitis media and acute lower respiratory tract infection in infancy.\textsuperscript{2, 42} In older children the rates of leukaemia are greater, as are cholesterol levels and hypertension and type 1 or type 2 diabetes.\textsuperscript{2, 42, 41}

**CONVENTION ON THE RIGHTS OF THE CHILD**

Article 24 of the Convention on the Rights of the Child emphasises the need to diminish infant and child mortality and ensure that parents are supported in the knowledge of the advantages of breastfeeding.\textsuperscript{44} Although all but two countries, Somalia and the USA, have ratified the Convention, many have not yet drafted legislation on the health and welfare of children, and few have statutes supporting the rights of women to nurse their infants at their workplace.\textsuperscript{19, 45}

**MOTHER-TO-CHILD TRANSMISSION OF HIV**

In 1985 breast milk was found to transmit HIV and infected mothers were advised to use breast milk substitutes.\textsuperscript{46} Formula companies responded by promoting the dangers of breastfeeding and providing free formula in the developing world.\textsuperscript{47} However in resource-poor countries substitute feeding increases the risk of dying in the first 7 months of life.\textsuperscript{48, 49} Some doctors insist that free formula can be made ‘safe’ in poor countries.\textsuperscript{50} However, supplies may become unavailable, and contamination and overdilution are frequent problems resulting in diarrhoea, malnutrition and increased mortality.\textsuperscript{19, 48, 51, 53}

The WHO\textsuperscript{52} Guidelines on HIV and Infant Feeding\textsuperscript{2010} recommends exclusive breastfeeding for 6 months with antiretroviral treatment for the mother. Substitute feeding is recommended if, and only if, it is acceptable, feasible, affordable, sustainable and safe.\textsuperscript{53} In resource-poor countries the introduction of these guidelines has not resulted in an increase in the postnatal transmission of HIV or mortality by 18 months.\textsuperscript{49, 51, 52}

**APPROPRIATE USE OF FORMULA**

In some instances formula feeding is clearly essential: when the mother has to take cytotoxic or potentially toxic drugs, or is unwilling or unable to breastfeed.\textsuperscript{54} In addition, mothers of preterm infants requiring prolonged hospitalisation can rarely produce sufficient milk.\textsuperscript{54} Surprisingly, in the 2005 UK Infant Feeding Survey only 13% of mothers who were weaning their infants were following the correct instructions for preparation of formula.\textsuperscript{4} Healthcare providers need to be able to understand the appropriate use of formula and be available to teach mothers how to prepare it correctly.\textsuperscript{4, 54} In resource-poor countries WHO suggests heat-treated donor breast milk for infants less than 6 months of age—a complicated alternative.\textsuperscript{52} Modified animal milk is not advised, but might occasionally be the only possible choice.

**SUMMARY**

The aggressive marketing of breast milk substitutes results in increased child morbidity and mortality, especially in resource-poor countries. The WHO Code was designed to prohibit such advertising, but the resources of the formula industry remain almost inexhaustible. All health workers need to promote and support breastfeeding, know and understand the Code, and report violations and thus improve child survival throughout the world.

**Contributors**

JPB is a Clinical Professor of Pediatrics at the University of California, San Francisco. She is a retired neonatologist with major interests in the use of human milk in the intensive care nursery and in the control of ventilation in the newborn infant. She spent 11 years in Africa teaching paediatrics at the University of Nairobi and the University of Zimbabwe.

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**Figure 1**

Billboard in central Vientiane, Laos. (Translation: Bear Brand Formula Milk; Advanced; New development; For everyone; Nestlé Brings Good Food, Good Life). Photo courtesy of Bryan Watt, Health Frontiers, Laos.
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